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Biotechnology

Recent Biotech Developments in the EU

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Approved by:
Norval Francis
U.S. Mission to the EU

Prepared by:
Stan Cohen

Report Highlights:
The new EU Commission has decided to engage in a policy debate on biotech sometime during the next 2 months. Faced with a number of challenges to its regulatory approach to biotech, the Commission's decision to undertake the debate has likely been prompted by a number of contentious and unresolved issues:
--the inability to get member states to approve biotech events and to overturn marketing bans dating back to 1997;
--the emergence of trade-restricting member state proposals for national coexistence laws;
--Hungary's recent banning of the planting of MON810;
--the absence of seed labeling legislation for the presence of biotech seed;
--and finally, about 30 biotech events in the pipeline awaiting approval.

Includes PSD Changes: No
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Biotech Regulatory Process

Many of the contentious biotech issues now confronting the EU are not related to human health and environmental safety. Over the last 6 years the EU has implemented a comprehensive regulatory system to ensure that biotech products are fully evaluated to ensure their safety. The EU Commission, the European Food Safety Authority (EFSA) and the member state competent authorities have the final say before a product is authorized for release on the market.

Now the EU and the member states are deadlocked over a number of issues that are based more on economic considerations, and not safety: 1) the on-going search for seed labeling legislation for biotech seed commingled with conventional seed and 2) the development of coexistence measures for biotech, conventional and organic agriculture that equally protect the interests of all farmers. Similarly, the EU Commission has stated that the marketing bans in 6 member states are not based on legitimate safety concerns.

Status of Biotech Approvals

Syngenta's Bt11 sweet corn for human consumption was authorized for marketing in May 2004. Monsanto's NK603 herbicide tolerant corn was authorized in November 2004 for import for both food and feed uses. These are the only biotech products that the EU has authorized for marketing since 1998.

Currently, there are about 30 biotech events in the pipeline for approval. Those furthest along in the process are presented in the following table.

Event	Company	Use	Risk Assessment	Status
Herbicide Tolerant Rapeseed, GT73	Monsanto	Import/Processing/Feed	Positive	At Commission for Final Consent
MON863 Corn, Insect Resistance	Monsanto	Import/Processing/Feed/Food	Positive	Commission to Refer to Council & Regulatory Cmt. Decision (food)
Herbicide Tolerant Corn, GA21	Monsanto	Food	Positive	Regulatory Cmt. Decision, March
MON863XMON810 Corn, Insect Resistance	Monsanto	Import/Processing/Feed/Food	Pending	EFSA opinions pending
YieldGard/Roundup Ready Corn, Insect Resistance and Herbicide Tolerance	Monsanto	Import/Processing/Feed/Food	Pending	Rapporteur Review (Spain) and EFSA opinion pending

1507 Corn, Insect Resistance	Pioneer/ Mycogen	Import/Processing/Feed	Positive	Regulatory Cmt. Decision, March
Bt11 Corn, Insect Resistance	Syngenta	Cultivation	EFSA Opinion Pending	N/A
Herbicide Tolerant Hybrid Rapeseed (Ms8Rf3)	Bayer Crop Science	Import/Processing/Feed	SCP 1998 positive 1/	EFSA opinion pending
Herbicide Tolerant Rapeseed (T45)	Bayer Crop Science	Import/Processing	To be sent to EFSA	Application in UK since March 2004
Herbicide Tolerant Rice Liberty Link 62	Bayer Crop Science	Import/Processing/Food/Feed	EFSA opinions pending	N/A
Herbicide Tolerant Cotton Liberty Link 25	Bayer Crop Science	Import/Processing/Feed/Food	To be sent to EFSA	Applications in Spain, 3/2004 and NL, 3/2005

1/ Positive risk assessments issued under the old Scientific Committee on Plants (SCP) under Directive 90/220.

No EU regulatory committee made up of the member states has voted in favor of authorizing the marketing of a product despite consistently positive risk assessments from EFSA.

For both BT 11 and NK 603, the Commission recommended that the member states authorize the marketing of these products based on the positive risk assessments issued. Despite this the member states failed to reach a qualified majority for or against approval, and the Commission then asked the Council of Ministers to come to a decision. After 3 months, the Council also deferred and sent the matter back to the Commission. The Commission then authorized the marketing of the two biotech events.

The Council of Minister's involvement in the approval process for biotech events is a dramatic departure from normal legislative procedures. Agriculture Ministers meet to approve major CAP reforms or EU trade policy positions in the WTO Doha round. Typically, working level officials drawn from the member states consulting in a regulatory committee would make decisions on biotech events.

Reportedly, Health and Consumer Protection Commissioner Markos Kyprianou has expressed frustration with the inability of the member states to reach agreements on biotech approvals despite comprehensive traceablility and labeling regulations and positive risk assessments.

Member State Marketing Bans

Marketing bans for a number of events remain in effect in effect in Austria, Denmark, France, Luxembourg, Germany, and Greece. In November 2004, EU member states met in a regulatory committee to review the Commission's proposal recommending the lifting of the bans. The Commission based its recommendation on EFSA opinions asserting that there was no scientific basis for the member state bans. Nevertheless, the regulatory committee failed to reach a decision and the Commission has referred the matter to the Council who has three months to make a decision. (It is expected that the March 10 Environment Council will

consider the proposal.) Since it is likely the Council will fail to reach a decision, the Commission will then be able to lift the bans.

The events banned are presented in the following table. The Commission had approved these products for marketing based on positive risk assessments issued by EU scientific committees.

Country	Event Banned	Date of Ban
Austria	Syngenta Bt176 Corn, Bayer T25 Corn, Monsanto MON810 corn	1997, 2000, 1999
France	Bayer Rapeseeds Topas 19/2 and MS1XRf1	1998 for both
Germany	Syngenta Bt176 corn	2000
Greece	Bayer Rapeseed Topas 19/2	1998
Luxembourg	Syngenta Bt176	1997

MON810 and the EU Seeds Labeling Proposal

In September 2004, the EU Commission approved the inscription of 17 varieties of Monsanto's biotech corn (MON810) into the EU common catalogue for seeds. Seed of varieties in the common catalogue can be marketed in the entire EU, whereas those in the national catalogues can only be marketed in the country concerned. The inscription of the MON810 varieties is the first time biotech varieties have been inscribed in the common catalogue.

MON810 corn has been approved in the EU since 1998. 17 varieties of corn derived from MON810 are inscribed in national catalogues: 6 in France and 11 in Spain. Typically, seeds entering the national catalogue are immediately entered into the EU common catalogue. However, a number of member states attempted to block this procedure, insisting that the Commission first develop labeling legislation for biotech seeds establishing maximum thresholds for the adventitious presence (AP) of biotech seed commingled with conventional and organic seed.

Citing the absence of a law for coexistence as the ostensible reason, the Hungarian government recently banned the planting of MON810. Like its neighbor, Slovakia is now also reportedly under pressure from various groups to ban MON810.

While the former Prodi College of Commissioners had also intended in September 2004 to propose a seed labeling amendment for the presence of GM seeds commingled with conventional seed, the different directorate generals (DG) couldn't reach agreement. Reportedly, DG Environment and DG Agriculture pressed for a maximum AP of 0.3 percent for corn whereas DG Health and Consumer Protection favored 0.5 percent. There was agreement of 0.03 percent for rapeseed. Faced with this impasse, the Prodi Commission called for additional research to determine the economic impact of different thresholds on farmers and seed producers before taking any further action. The Commission has been

trying to develop a policy on seed labeling since 2001 when the Scientific Committee on Plants presented recommendations on AP levels for a number of biotech seeds (corn--5 percent; soybeans--7 per cent; and rapeseed -- 3 percent).

In the absence of a EU seed labeling regulation for the presence of biotech seed, the Commission has stated "that since no thresholds for the AP of GMOs in conventional seed lots have been established, any seed lot containing GM seed authorized for the cultivation in the EU has to be labeled as containing GMOs. Seed lots containing GM seeds that are not authorized for cultivation, can not be marketed in the EU."

Some members of the new Barroso Commission appear to favor setting AP thresholds at the level of detection--0.1 percent. In his parliamentary hearings in September, Environment Commissioner Stavros Dimas voiced support for 0.1. Likewise, Agriculture Commissioner Mariann Fischer-Boel, one of the architects of Denmark's tough coexistence law and a strong proponent of organic agriculture, also reportedly favors very low thresholds.

Coexistence

Agriculture Commissioner Fischer-Boel has indicated that she is giving consideration to modifying the current Commission policy that encourages countries to develop their own guidelines for the coexistence of biotech and conventional agriculture. She has recently suggested the possibility of developing a EU "framework legislation" that would presumably impose tighter controls on farmers, and yet still allow some flexibility to account for differences among countries. This would mark a departure from the non-binding guidelines (http://europa.eu.int/comm/agriculture/res/index_en.htm) published by the Commission in July 2003. However before proposing any changes, Commissioner Fischer-Boel will await the results of a EU review of the experiences of the member states in developing coexistence laws due out in late 2005.

Austria, Denmark, and Italy have taken the lead in pressing the Commission to adopt a EU-wide regulation for the coexistence of biotech crops and conventional and organic agriculture. Along with Germany, each of these countries has drafted coexistence laws that are extremely restrictive in terms of what farmers of biotech crops are required to do. Faced with such challenges, farmers will likely not run the risk of planting biotech crops. Moreover, certain aspects of these laws would appear to violate the internal market rules of the EU which guarantees "free circulation", and is reiterated in Article 22 of Directive 2001/18/EC which regulates the deliberate release into the environment of genetically modified organisms. In the past, the Prodi Commission has been critical of Germany's proposed coexistence law.

The New Commission's Policy on Biotech

The new Commission has decided to engage in a policy debate on biotech sometime during the next 2 months. The Commissioners (Agriculture, Environment, Health and Consumer Protection, Research, and Trade) responsible for biotech will reportedly hold an initial discussion on the subject, and then share its conclusions with the College of Commissioners.

Faced with a number of challenges to its regulatory approach to biotech, the Commission's decision to undertake the debate has likely been prompted by a number of contentious and unresolved issues:

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